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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,831	10/15/2001	Christophe Bonny	20349-512 (OTT-12)	4526

7590

06/06/2003

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 06/06/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Restriction Purposes Only

Application No.

09/977,831

Applicant(s)

Bonny

Examiner

Padmashri Ponnaluri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. Claims 1-35 are currently pending in this application.

Please Note: In an effort to enhance communication with our customers and reduce processing time, a dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Andrew Wang, Supervisory Patent Examiner at andrew.wang@uspto.gov or 7(703)306-3217. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 3-13, 19-21 and 28, drawn to a transporter comprising amino acid sequence $XmRX_oRXn$ and a composition coupled to an effector and a kit comprising the pharmaceutical composition, classified in class 530, subclass 300+ or class 514, subclass 14.

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- II. Claims 1, 3-13, 19-21 and 28, drawn to a transporter comprising amino acid sequence $XmRRRX_n$, and a composition coupled to an effector and a kit comprising the pharmaceutical composition, classified in class 530, subclass 300+.
- III. Claims 1, 3-13, 19-21 and 28, drawn to a transporter comprising amino acid sequence $XmRRXRX_n$ and a composition coupled to an effector, and a kit comprising the pharmaceutical composition, classified in class 530, subclass 300+.
- IV. Claims 1, 3-13, 19-21 and 28, drawn to a transporter comprising amino acid sequence $XmRXRRX_n$ and a kit comprising the pharmaceutical composition, and coupled to an effector, classified in class 530, subclass 300+.
- V. Claim 2, drawn to a transporter comprising amino acid sequence $RXXR$ (different from the amino acid sequences recited in claim 1), classified in class 530, subclass 330.
- VI. Claim 14, drawn to a method of translocating the transporter peptide across the membrane of pancreatic B-cells, classified in class 530, subclass 300+.
- VII. Claim 15, drawn to a method of translocating the transporter peptide across the membrane of hepatocytes, classified in class 530, subclass 300+.
- VIII. Claim 16, drawn to a method of translocating the transporter peptide across the membrane of colon cells, classified in class 530, subclass 300+.
- IX. Claim 17, drawn to a method of translocating the transporter peptide across the membrane of muscle cells, classified in class 530, subclass 300+.

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- X. Claim 18, drawn to a method of translocating the transporter peptide across the membrane of lung cells, classified in class 530, subclass 300+.
- XI. Claim 22, drawn to a method of producing a translocatable conjugate, classified in class 424, subclass 178.1.
- XII. Claims 23-25, drawn to a method of translocating an effector into cytoplasm and nucleus of a eukaryotic cell, classified in class 530, subclass 300+.
- XIII. Claims 26-27, drawn to a method of increasing the intracellular concentration of an effector within a eukaryotic cell, classified in class 530, subclass 300+.
- XIV. Claims 29-30, drawn to a method of treating a disease, classified in class 530, subclass 300+.
- XV. Claims 29-30, drawn to a method of preventing a disease, classified in class 530, subclass 300+.
- XVI. Claims 31-34, drawn to a method of screening a phage library for transporter peptides, classified in class 530, subclass 300+.

Groups 17-40. Claim 35, each group is drawn to a peptide of sequence 1-34, classified in class 530, subclass 300+.

NOTE that the Kit comprising a pharmaceutical agent would only be examined with either groups I-IV, if the elected effector is a pharmaceutical agent.

II. The inventions are distinct, each from the other because of the following reasons:

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- a). Inventions of groups I- V and groups 17-40 are all drawn to different products. These distinct products are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The peptides differ in amino acid composition. Thus, restriction between the compounds is proper.
- b). Inventions of groups VI-XVI are all drawn to different methods which are distinct from one another. The different methods are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Thus, restriction between the compounds is proper.
- c). Inventions of groups I-V, 17-40 and groups VI-XVI are all drawn to different products and methods of use of the different products in different methods. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the different peptides are used in different methods. Thus, the restriction between the groups is proper.
- d). Should applicant traverse on the ground that the method inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the method inventions to be obvious variants or clearly admit on the record that this is the case. In

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either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

e) Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Even though some of the groups are classified in the same class/subclass, this has no effect on the non-patent literature search. Different inventions or groups would require completely different searches in non-patent databases, and there is no exception that the searches would be co-extensive. Therefore, these do not create an undue search burden, and restriction for examination purposes as indicated is proper.

f) This application contains claims directed to the following patentably distinct species of the claimed invention: Depending on the elected group applicants are requested to elect a single species for each of the following:

A) If either groups I-IV are elected, applicants are requested to elect a single species for each of the following,

- a) amino acid representing X;
- b) a specific group or amino acid representing R, (NOTE **R** is not defined in the claim);
- c) a specific integer for m, n, o;
- d) length of peptide sequence;

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- e) a specific group of effector;
 - f) if the elected effector is a pharmaceutical agent, one specific pharmaceutical agent;
 - g) one species of tissue in claim 13.
- B) If group V is elected, applicants are requested to elect a single amino acid sequence representing RXXR.
- C) If group VI is elected, applicants are requested to elect a single peptide sequence.
- D) If group VII is elected, applicants are requested to elect a single peptide sequence.
- E) If group VIII is elected, applicants are requested to elect a single peptide sequence.
- F) If group IX is elected, applicants are requested to elect a single peptide sequence.
- G) If group X is elected, applicants are requested to elect a single peptide sequence.
- H) If group XI is elected, applicants are requested to elect a single peptide sequence.
- I) If group XII is elected, applicants are requested to elect a single peptide sequence; and a single species of effector.
- J) If group XIII is elected, applicants are requested to elect a single peptide sequence and a single species of effector.
- K) If either group XIV or XV is elected, applicants are requested to elect a single peptide sequence which forms the pharmaceutical composition; and a single species of disease.
- L) If group XVI is elected, applicants are requested to elect a single phage display library (note the claim do not recite any specific peptides).

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For this response to be complete and for search purposes, applicants should provide the chemical structure of elected compounds (or species), wherein each specific formula substituents of each of the above identified elected species are defined either by picture, or by expressing the species in terms of the variables of the formula.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CAR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

g) Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CAR 1.143).

h) Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CAR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a request under 37 CAR 1.48(b) and by the fee required under 37 CAR 1.17(I).

i) Applicant is required to reply to this restriction requirement within 30 days of mailing this action. See MPEP 809.2(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on *Increased Flex Schedule* and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Primary Examiner
Technology Center 1600
Art Unit 1639
02 June 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER